

January 21, 2021

Ms. Susanne Galin  
Stryker Instruments  
2505 Avenue Dalton  
Quebec, QC G1P3S5  
Canada

Dear Ms. Galin:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).<sup>1</sup> Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.<sup>2</sup>

On April 14, 2020, based on your<sup>3</sup> request, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of Stryker Instrument's Sterizone VP4 Sterilizer<sup>4</sup> (hereafter "STERIZONE VP4 Sterilizer") N95 Respirator Decontamination Cycle ("STERIZONE VP4 N95 Respirator Decontamination Cycle") for use in decontaminating compatible N95 respirators<sup>5</sup> for single-user reuse<sup>6</sup> by healthcare personnel

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<sup>1</sup> U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3, 85 FR 7316 (February 7, 2020).

<sup>2</sup> U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 17335 (March 27, 2020).

<sup>3</sup> For ease of reference, this letter will use the term "you" and related terms to refer to Stryker Instruments.

<sup>4</sup> This EUA, as originally issued on April 14, 2020, authorized the emergency use of the Sterizone VP4 Sterilizer for the otherwise unapproved use to decontaminate compatible N95 or N95-equivalent respirators for single-user reuse using the STERIZONE VP4 N95 Respirator Decontamination Cycle. The Sterizone VP4 Sterilizer is 510(k)-cleared (K172191, K173694, and K153392) for use in terminal sterilization of cleaned, rinsed, and dried metal and non-metal reusable medical devices in healthcare facilities.

<sup>5</sup> In the April 14, 2020 letter, "compatible N95 respirators" were defined as any N95 or N95-equivalent respirators that do not contain cellulose-based materials. The April 14, 2020 letter also defined "N95-equivalent respirators" as respirators identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators and identified in Appendix A of the EUA for Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China, available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

<sup>6</sup> Single-user reuse means that the same respirator is returned for reuse to the same healthcare personnel following

(HCP)<sup>7</sup> to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of filtering facepiece respirators (FFRs) resulting from the COVID-19 pandemic.

On June 6, 2020, FDA reissued the April 14, 2020 letter in order to revise which compatible N95 respirators<sup>8</sup> this decontamination system was authorized to decontaminate in order to address public health and safety concerns regarding certain respirators.

On January 21, 2021, in response to public health and safety concerns regarding the decontamination of certain respirators, FDA is reissuing the June 6, 2020 letter in order to revise the authorization of the STERIZONE VP4 Sterilizer to include the following aspects:

1. Limitation of the respirator features that are considered to be compatible N95 respirators<sup>9</sup> in which this decontamination system is authorized to decontaminate.
2. Incorporation of a post-authorization study to collect real-world evidence (RWE) to verify that compatible N95 respirators are capable of adequate reuse after 2 decontamination cycles.<sup>10</sup>

The STERIZONE VP4 Sterilizer is no longer authorized to decontaminate compatible N95 respirators with antimicrobial agents or a duck-billed design. Additionally, a Condition of Authorization (Section IV.L) has been added in which you must conduct a post-authorization

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decontamination. FDA has revised this to be clearer and notes that this clarifying edit does not change the Scope of Authorization. This previously read: “single-user reuse means that the same Healthcare Personnel should use the respirator following decontamination.”

<sup>7</sup> For purposes of this EUA, HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

<sup>8</sup> In the June 6, 2020 letter, “compatible N95 respirators” were defined as non-cellulose containing respirators that do not have an exhalation valve that are either: (1) authorized in the NIOSH-Approved Air Purifying Respirators EUA; or (2) authorized and identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, which are available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>. As described in the Scope of Authorization (Section II) of the June 6, 2020 letter, the STERIZONE VP4 N95 Respirator Decontamination Cycle was no longer authorized to decontaminate respirators that are authorized under the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA or authorized respirators that have exhalation valves.

<sup>9</sup> For purposes of this revised EUA, “compatible N95 respirators” are defined as any non-cellulose containing respirators that do not have an exhalation valve, antimicrobial agents, or a duck-billed design, and that are either: (1) authorized in the NIOSH-Approved Air Purifying Respirators EUA; or (2) authorized and identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, which are available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>. Please see FDA’s website for further information on N95 respirators, available at <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks>.

<sup>10</sup> Other minor corrections and clarifications have also been made during the review and edit process for reissuance of the January 21, 2021 letter.

study to verify that compatible N95 respirators are adequate for reuse following 2 decontamination cycles. The maximum number of cycles can be increased following submission and review of RWE for greater than 2 decontamination cycles (see Section IV.M). These revisions are reflected in the Scope of Authorization (Section II), Conditions of Authorization (Section IV), and authorized labeling. Having concluded that revising the June 6, 2020 letter is appropriate to protect the public health or safety under Section 564(g)(2)(C) of the Act, FDA is reissuing the June 6, 2020 letter in its entirety with the revisions incorporated.

The Sterizone VP4 Sterilizer is 510(k)-cleared (K172191, K173694, and K153392) for use in terminal sterilization of cleaned, rinsed, and dried metal and non-metal reusable medical devices in healthcare facilities. The Sterizone VP4 Sterilizer is not cleared, approved, or subject to an approved investigational device exemption for use in decontaminating compatible N95 respirators, and therefore, requires authorization for such use. Additionally, there are no FDA approved or cleared devices for decontaminating compatible N95 respirators, which are needed for use by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic. FDA has reviewed the totality of scientific evidence available, including testing that was submitted within previous applications supporting device clearance for other uses that spanned more than 21 different types of polymer materials, including materials consistent with those found in compatible N95 respirators. FDA has leveraged the performance data (e.g., half cycle test, sporicidal test, compatibility, residual analysis, functionality) from the previous submissions to support that the emergency use, which repurposes the Stryker STERIZONE VP4 Sterilizer to be used for compatible N95 respirators, may be effective.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of the STERIZONE VP4 N95 Respirator Decontamination Cycle, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

#### **I. Criteria for Issuance of Authorization**

I have concluded that the emergency use of the STERIZONE VP4 N95 Respirator Decontamination Cycle, as described in the Scope of Authorization (Section II) of this letter, for decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms during the COVID-19 pandemic meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the STERIZONE VP4 N95 Respirator Decontamination Cycle may be effective at preventing exposure to pathogenic biological airborne particulates by decontaminating, for a maximum of 2 decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic

microorganisms, and that the known and potential benefits of this device, when used for such use, outweigh the known and potential risks; and

3. There is no adequate, approved, and available alternative to the emergency use of the STERIZONE VP4 N95 Respirator Decontamination Cycle for decontaminating compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates during FFR shortages during the COVID-19 pandemic.<sup>11,12</sup>

## **II. Scope of Authorization**

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the STERIZONE VP4 N95 Respirator Decontamination Cycle, for use in decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, for a maximum of 2 decontamination cycles per respirator, for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

The STERIZONE VP4 N95 Respirator Decontamination Cycle is not authorized for use in decontaminating incompatible N95 respirators. N95 respirators containing cellulose-based materials, and respirators that have exhalation valves, antimicrobial agents, and duck-billed design are incompatible with the STERIZONE VP4 N95 Respirator Decontamination Cycle. This system is also not authorized to decontaminate respirators authorized by the non-NIOSH-approved Filtering Facepiece Respirator manufactured in China EUA.

### Authorized Product

The STERIZONE VP4 Sterilizer is a self-contained stand-alone device, using vaporized hydrogen peroxide and ozone in a multiphase process. The STERIZONE VP4 N95 Respirator Decontamination Cycle offers a single sterilization cycle that is FDA-cleared for general instruments, flexible endoscopes, and rigid-channel devices. Under this emergency use authorization, the authorized product's single pre-programmed cycle is authorized for use to decontaminate up to twenty (20) compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms so that the respirators can be reused by the original HCP (i.e., single-user).

The STERIZONE VP4 N95 Respirator Decontamination Cycle uses any Tyvek pouch that has been FDA-cleared for use in hydrogen peroxide applications. Cellulose-based pouches cannot be used.

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<sup>11</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

<sup>12</sup> There are not sufficient quantities of FFRs to meet the needs of the U.S. healthcare system. These disposable N95 respirators are an integral part of routine patient care. Due to shortages of N95 respirators, HCP may need to treat patients without personal protective equipment (PPE) or use a bandana or other less effective masks unless single-use N95 respirators can be decontaminated for reuse. Providing a method for decontaminating compatible N95 respirators reduces stress on the supply chain and helps meet the needs of the healthcare system. Providing HCP who are on the forefront of the COVID-19 response with FFRs is necessary in order to reduce the risk of illness in HCP and increase their availability to provide care to affected patients or those suspected of having COVID-19.

The Sterizone Chemical Indicator (cleared in K141698) for the Sterizone VP4 Sterilizer must be placed in the chamber to verify sterilant exposure. Following completion of the cycle, the chemical indicator's color is compared to the "PASS" reference color. If the colors matched or the color present is lighter, the compatible N95 respirators have been exposed to the vaporized hydrogen peroxide. The respirators may be used after a 24-hour aeration period. If the indicator does not match the "PASS" criteria, the compatible N95 respirators will not be considered decontaminated and either rerun through the STERIZONE VP4 N95 Respirator Decontamination Cycle or discarded. Any visibly soiled or damaged respirators will not be decontaminated in the STERIZONE VP4 N95 Respirator Decontamination Cycle and shall be immediately discarded.

Available scientific information indicates that compatible N95 respirators can be decontaminated two times using the STERIZONE VP4 N95 Respirator Decontamination Cycle. Compatible N95 respirators can be decontaminated a maximum of two times by this process. The pouches may be decontaminated one time. The number of decontamination cycles is recorded on the respirator. If at any time, this identification becomes illegible for any reason, the respirator shall be discarded.

The above described product is authorized to be accompanied with the following product-specific information (that will be made available at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>) pertaining to emergency use, and is required to be made available to healthcare personnel and healthcare facilities, respectively:

- Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination by the STERIZONE VP4 Sterilizer Using the Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle;
- Instructions for Healthcare Facilities: Emergency Use Decontamination of Compatible N95 Respirators in Stryker's STERIZONE VP4 Sterilizer Using the Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle.

In addition, following decontamination, compatible N95 respirators decontaminated by the authorized product must be accompanied by the following labeling, developed by Stryker, upon return of the respirators to the appropriate single-user HCP:

- Fact Sheet for Healthcare Personnel: STRYKER Decontamination Cycle for Decontaminating Compatible N95 Respirators.

The Fact Sheet for Healthcare Personnel, Instructions for Healthcare Personnel, Instructions for Healthcare Facilities, and the following previously cleared labeling are referred to as "authorized labeling":

- STERIZONE VP4 Sterilizer User Manual;
- STERIZONE VP4 Test Pack Instructions for Use (MA-900-066);
- STERIZONE BI+ Indicator Instructions for Use (MA-900-043); and
- STERIZONE CI+ instructions for use (MA-900-044).

The above described product, when accompanied with the described labeling is authorized to be distributed to and administered under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the STERIZONE VP4 N95 Respirator Decontamination Cycle, when used and labeled consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the STERIZONE VP4 N95 Respirator Decontamination Cycle may be effective at decontaminating compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during FFR shortages during the COVID-19 pandemic, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the STERIZONE VP4 N95 Respirator Decontamination Cycle, when used to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the STERIZONE VP4 N95 Respirator Decontamination Cycle must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, the STERIZONE VP4 N95 Respirator Decontamination Cycle is authorized for emergency use, as described in the Scope of Authorization (Section II).

### **III. Waiver of Certain FDA Requirements**

Pursuant to Section 564(e)(3) of the Act, with respect to the emergency use of a product for which an authorization under this section is issued, FDA may waive or limit, to the extent appropriate given the circumstances of the emergency, requirements regarding good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulations under this Act, including such requirements established under Section 520(f)(1) of the Act. FDA grants that waiver, including the quality system requirements under 21 CFR Part 820.

### **IV. Conditions of Authorization**

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Stryker Instruments (Stryker)

- A. Stryker must comply with the labeling requirements under 21 CFR 801 Subpart A (general labeling provisions), as well as those described in Section II of this letter, the Scope of Authorization.
- B. Stryker must provide to all healthcare facility customers the authorized labeling before the decontamination process begins.
- C. Stryker must notify all healthcare facility customers about the conditions of this authorization applicable to healthcare facilities before the decontamination process begins.
- D. Stryker may request changes to this EUA for the STERIZONE VP4 Sterilizer<sup>13</sup>, including changes to the authorized labeling. Any request for changes to this EUA must be submitted to the Division of Infection Control and Plastic and Reconstructive Surgery (DHT4B)/Office of Health Technology 4: Office of Surgical and Infection Control Devices (OHT4)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH). Such changes require appropriate authorization from FDA prior to implementation.
- E. Stryker may request and be allowed to add compatible N95 respirator models under Condition D. To support such a request, Stryker must provide to FDA validation data to support new respirator models.
- F. Stryker may request and be allowed to increase the maximum capacity of 20 compatible N95 respirators per decontamination cycle under Condition D. To support such a request, Stryker must provide FDA validation data to support the increased decontamination capacity.
- G. Use of the STERIZONE VP4 N95 Respirator Decontamination Cycle on other types of personal protective equipment is not authorized and would require a request for a separate EUA or marketing authorization and data supporting such other use.
- H. Stryker will have a process in place and adequate Medical Device Reporting procedures in accordance with 21 CFR 803, to report to FDA adverse events of which Stryker becomes aware related to the STERIZONE VP4 N95 Respirator Decontamination Cycle and compatible N95 respirators that have undergone decontamination using the STERIZONE VP4 N95 Respirator Decontamination Cycle (“the decontaminated, compatible N95 respirators”). This includes, but is not limited to, reports from healthcare facilities concerning infection or

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<sup>13</sup> The following types of revisions may be authorized without reissuing this letter: (1) non-substantive editorial corrections to this letter; (2) new types of authorized labeling, including new fact sheets; (3) new carton/container labels; (4) changes to manufacturing processes, including tests or other authorized components of manufacturing; (5) new conditions of authorization to require data collection or study; (6) new instruments, associated software, components or materials in the authorized product or modifications in the way that the device is used. For changes of the type listed in (5) or (6), review and concurrence is required from the Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist.

potential infection of the healthcare facility personnel involved in the use of STERIZONE VP4 N95 Respirator Decontamination Cycle and users of the decontaminated, compatible N95 respirators. Other examples of reportable events that may be relevant to the authorized product include, but are not limited to: allergic reactions or eye, mouth, or nose irritation, evidence that a decontaminated, compatible N95 respirator is unable to perform its essential function, events related to residuals or user contact with residuals (if applicable), infection in decontaminated, compatible N95 respirator wearers, or concerns with the process control or malfunctions of the authorized product used to decontaminate the compatible N95 respirators.

- I. Stryker will have a process in place to collect information on the performance of STERIZONE VP4 N95 Respirator Decontamination Cycle, including information regarding degradation of decontaminated, compatible N95 respirators, and evaluate this information to determine if adverse event reporting in accordance with 21 CFR Part 803 is warranted.
- J. Stryker will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.
- K. Stryker is authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.
- L. Stryker must collect and submit to FDA real-world use data for FDA review to confirm the continued fit and performance of compatible N95 respirators authorized under this EUA after undergoing two (2) cycles of decontamination. The authorized maximum number of two (2) decontamination cycles per compatible N95 respirator (Scope of Authorization (Section II)) will be maintained or revised based on the real-world use data.

You must complete your study within 60 days of the date of this letter or before 1500 compatible N95 respirators have been decontaminated using your system, whichever is later. You may seek an extension to complete your study where agreed upon by DHT4B/OHT4/OPEQ/CDRH. Your results must be submitted to DHT4B/OHT4/OPEQ/CDRH for review within 15 days of the study completion. Upon completion of FDA's review, you must publish the study results on your website.

At minimum, the study design must include the following testing with acceptance criteria and sampling:

1. **Fit Testing (Required)**
  - a. Acceptance Criteria:  $\geq 70\%$  of the subjects pass
  - b. Sampling: Minimum of 10 representative<sup>14</sup> compatible N95 respirators (minimum of 5 male and 5 female subjects) following 2 decontamination cycles.

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<sup>14</sup> Samples must be collected for testing after the 2<sup>nd</sup> decontamination cycle (which is after the 3<sup>rd</sup> use, to confirm through real-world use data that respirators can withstand 2 cycles of decontamination and reuse). Test samples must include a representative variation of respirators that you are receiving for decontamination. Justification must be provided for the sample chosen, including materials, design characteristics, sizes, etc. Records regarding sample

- c. Test Design: OSHA guidelines [OSHA 1910.134 Appendix A Fit Testing Protocol](#)<sup>15</sup>
  2. **Filtration Efficiency (Required)**
    - a. Acceptance Criteria:  $\geq 95\%$
    - b. Sampling: Minimum of 10 representative<sup>14</sup> compatible N95 respirators following 2 decontamination cycles.
    - c. Test Design: CDC guidelines [Assessment of Filter Penetration Performance and Fit for Decontaminated N95 Respirators, Section "Particulate Filter Efficiency Testing" on Page 5](#)<sup>16</sup>
  3. **Indelible Markings (Required)**
    - a. Acceptance Criteria: Markings must be clearly legible.
    - b. Sampling: Minimum of 10 representative<sup>14</sup> compatible N95 respirators from Fit Testing following 2 decontamination cycles.
    - c. Test Design: Respirators must be visually inspected prior to Fit Testing. An agreement will be met between 2 people evaluating legibility with a form to complete with “yes” or “no” on legibility.
- M. Following completion of Condition L, Stryker may request and be allowed to increase the maximum number of decontamination cycles per compatible N95 respirator under Condition D. To support such a request, Stryker must provide to FDA information regarding, filtration efficiency and respirator fit testing based on RWE, including, but not limited to, evidence collected in the study design and methods adopted in accordance with Condition L.

#### Healthcare Facilities

- N. Healthcare facilities shall notify Stryker when they intend to use the STERIZONE VP4 N95 Respirator Decontamination Cycle for the emergency use, consistent with Section II of this letter.
- O. Healthcare facilities shall make available to HCP who are or may be using the decontaminated, compatible N95 respirators the authorized Fact Sheet for Healthcare Personnel and Instructions for Healthcare Personnel that is required to be provided by Stryker.
- P. Healthcare facilities will have a process in place to report adverse events of which they become aware related to the STERIZONE VP4 N95 Respirator Decontamination Cycle and the decontaminated, compatible N95 respirators in accordance with 21 CFR Part 803. This includes, but is not limited to, monitoring healthcare facility personnel using the STERIZONE VP4 N95 Respirator Decontamination Cycle and HCP using the decontaminated, compatible N95 respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and reporting such infections. Other examples of reportable events that may be relevant to the authorized product include, but are not limited to: allergic reactions or eye, mouth, or nose irritation, evidence that a decontaminated, compatible N95 respirator is unable to perform its essential function, events related to residuals or user contact with

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type, model, materials, number of decontamination cycles, etc., must be kept for each sample tested.

<sup>15</sup> <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA>.

<sup>16</sup> [https://www.cdc.gov/niosh/npptl/respirators/testing/pdfs/NIOSHApproved\\_Decon\\_TestPlan10.pdf](https://www.cdc.gov/niosh/npptl/respirators/testing/pdfs/NIOSHApproved_Decon_TestPlan10.pdf).

residuals (if applicable), infection in decontaminated, compatible N95 respirator wearers, or concerns with the process control or malfunctions of the authorized product used to decontaminate the compatible N95 respirators.

- Q. Healthcare Facilities must inspect the decontaminated, compatible N95 respirators following the decontamination process using the STERIZONE VP4 N95 Respirator Decontamination Cycle. Any discoloration or other signs of degradation with a decontaminated, compatible N95 respirator shall promptly be reported to Stryker, and the healthcare facility must discard the respirator.
- R. Healthcare Facilities must track the number of times a compatible N95 respirator is decontaminated, up to a maximum of 2 decontamination cycles per compatible N95 respirator. Any decontaminated compatible N95 respirator that has exceeded 2 decontamination cycles shall be discarded. Healthcare Facilities must ensure that the decontaminated compatible N95 respirator is returned to its previous user.
- S. Healthcare facilities must maintain documentation for use of the STERIZONE VP4 N95 Respirator Decontamination Cycle consistent with current healthcare facility protocols. Healthcare facilities must maintain documentation that critical process parameters were met to achieve decontamination of compatible N95 respirators for each cycle. Healthcare facilities shall maintain this documentation associated with this EUA until otherwise notified by FDA. Such documentation will be made available to FDA upon request.

#### Conditions Related to Advertising and Promotion

- T. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in Section 502(a) and (q)(1) and (r) of the Act and FDA implementing regulations.
- U. No descriptive printed matter, advertising, or promotional materials relating to the use of your product may represent or suggest that such products are safe or effective for the decontamination of compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates.
- V. All descriptive printed matter, advertising, and promotional materials relating to the use of your product clearly and conspicuously shall state that:
- the STERIZONE VP4 N95 Respirator Decontamination Cycle has neither been cleared or approved by FDA, but has been authorized for emergency use by FDA under an EUA for the decontamination of compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates;
  - the emergency use of the STERIZONE VP4 N95 Respirator Decontamination Cycle is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 outbreak

under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

**V. Duration of Authorization**

This EUA will be effective until the declaration that circumstances exist justifying the authorization is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration

Enclosures

REVOKED